REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following remarks.

I. Status of the Claims

Claims 99-100 and 103-119 are currently pending in the application, with claims 99, 118 and 119 being the independent claims. Claims 98, 101 and 102 are canceled without prejudice to or disclaimer of the subject matter therein. Claims 100, 104, 106-117 and 119 have been withdrawn from consideration pursuant a restriction requirement. Thus, claims 99, 103, 105 and 118 are under consideration.

II. The Amendments to the Claims

Claim 99 is amended to be in independent form, as recommended by the Examiner. Support for the amendment to claim 99 may be found in claims 98-99 as previously presented.

Further, claims 103 and 118 are amended to delete the recitation of a polynucleotide comprising a naturally occurring polynucleotide sequence at least 90% identical to SEQ ID NO: 27 and a polynucleotide comprising a portion of the polynucleotide sequence of SEQ ID NO: 27 that specifically identifies SEQ ID NO: 27.

Finally, claims 100, 103-105, 108 and 116 are amended to depend from claim 99.

These amendments do not introduce any new matter into the application and their entry is respectfully requested.

III. The Objection to the Claims

The Office Action, at page 2, objects to claims 98-99, 101-103, 105 and 118 for reciting SEQ ID NO: 8. Without acquiescing to the propriety of the objection, claims 98 and 101-102

are canceled and claims 103 and 105 are amended to depend from claim 99. Thus, the objection is moot. Reconsideration and withdrawal of this ground of objection are respectfully requested.

IV. Priority

The Office Action, at page 2, states that no priority data is provided on the first page of the specification.

The foregoing amends the specification to insert priority data as requested by the Examiner.

V. The Rejection Under 35 U.S.C. § 112, Second Paragraph

The Office Action, at pages 2-3, rejects claims 98-99, 101-103, and 105-106 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite because of the recitation of the phrase "biologically active fragment" in claim 98 and the term "portion" in claim 103. Applicants respectfully traverse this ground of rejection.

Solely to advance prosecution and not in acquiescence with the propriety of the rejection, claim 98 is canceled and claim 103 is amended to delete the phrase "a polynucleotide comprising a portion of the polynucleotide sequence of SEQ ID NO: 27 that specifically identifies SEQ ID NO: 27". Accordingly, the rejection is moot. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

VI. The Rejection Under 35 U.S.C. § 112, First Paragraph

A. Enablement

The Office Action, at pages 3-5, rejects claims 98, 101-103, 105-106 and 118 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Office Action recognizes that the specification provides enablement for isolated polypeptides comprising SEQ ID NO: 6 and isolated polynucleotides/ RNA comprising SEQ ID

NO: 27. Nevertheless, the Office Action alleges that the specification does not provide enablement for: (a) biologically active and/or immunogenic fragments of SEQ ID NO:6; (b) isolated polynucleotides encoding these fragments; (c) isolated DNA/mRNA displaying 90% identity to SEQ ID NO: 27; and (d) isolated DNA/mRNA comprising a portion of SEQ ID NO: 27. Applicants respectfully traverse this ground of rejection.

M.P.E.P. Section § 2164.08 states the following with regard to enablement commensurate in scope with the claims:

> The Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without `undue experimentation'." *In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)*. Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991)*. All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. *See, e.g., In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)*.

With regard to the breadth of a claim, the M.P.E.P. states:

> As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. *In re Moore, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971)*.

Nevertheless, solely to advance prosecution, and not in acquiescence with the propriety of the rejection, the foregoing amends the pending claims to delete the recitation of biologically active and immunogenic fragments of SEQ ID NO: 6, isolated polynucleotides encoding the fragments and isolated polynucleotides displaying 90% identity to SEQ ID NO: 27 or comprising a portion of SEQ ID NO: 27. Accordingly, the rejection is moot.

Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

B. Written Description

The Office Action, at pages 5-7, rejects claims 98, 101-103, 105-106 and 118 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office Action alleges that the specification does not disclose the function of all polypeptide fragments and DNA/RNA fragments recited in the claims. Applicants respectfully traverse this ground of rejection.

The Federal Circuit has clarified the law regarding written description in *Faulkner-Gunter Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006). Specifically, the court held:

> 1) examples are not necessary to support the adequacy of a written description, 2) the written description standard may be met even when actual reduction to practice is absent; and 3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.

Id., at 1366. The Federal Circuit clarified issues particularly relevant for this application. The court favorably cites *LizardTech Inc. v. Earth Resource Mapping, PTY Inc.*, 424, F.3d 1336 (Fed. Cir. 2005), explaining that the specification is written for a person skilled in the art and it is unnecessary to spell out every detail of the invention, only enough is required to convince a person of skill in the art that the inventor possessed the invention and to enable the person to make and use the invention without undue experimentation. *Id.*

The court further clarifies, as provided in *Capon v. Eshlar* , 418 F. 3d 1349 (Fed. Cir 2005), that "the 'written description' requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed."

With regard to recitation of known structure, Faulkner explicitly holds: "it is the binding precedent of this court that Eli Lilly does not set forth a per se rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art." *Id* .

As stated above, solely to advance prosecution, and not in acquiescence with the propriety of the rejection, the foregoing amends the claims to delete the recitation of biologically active and immunogenic fragments of SEQ ID NO:6, isolated polynucleotides encoding the fragments, and isolated polynucleotides displaying 90% identity to SEQ ID NO: 27 or comprising a portion of SEQ ID NO: 27.

Claim 103, as amended, is directed to an isolated polypeptide of claim 99 encoded by a polynucleotide selected from the group consisting of: (i) a polynucleotide comprising a polynucleotide sequence of SEQ ID NO: 27; (ii) a polynucleotide comprising a polynucleotide complementary to the polynucleotide of (i); (iii) an RNA equivalent of the polynucleotide of (i); and (iv) polynucleotide of (i) further comprising a promoter sequence operably linked to the polynucleotide of (i).

Claim 118, as amended, is drawn to an isolated polynucleotide selected from the group consisting of: (i) a polynucleotide comprising a polynucleotide sequence of SEQ ID NO: 27; (ii) a polynucleotide comprising a polynucleotide complementary to the polynucleotide of (i); (iii) an RNA equivalent of the polynucleotide of (i); and (iv) a polynucleotide of (i) further comprising a promoter sequence operably linked to the polynucleotide of (i).

In the current application, Applicants have sufficiently disclosed the claimed invention to meet the written description requirement in line with the reasoning provided by the Federal Circuit. In fact, the specification provides a complete description of LIPAM polypeptide fragments of SEQ ID NOs:1-21 that are encoded by polynucleotide fragments of SEQ ID NOs:22-42 (*see* pages 15-18 of the published patent application publication).

In addition, the specification defines an "RNA equivalent," as "composed of the same linear sequence of nucleotides as the reference DNA molecule with the exception that all occurrences of the nitrogenous base thymine are replaced with uracil, and the sugar backbone is composed of ribose instead of deoxyribose" (*see* paragraph [0182] in the published patent application). Further, the specification teaches that "the polynucleotide sequences of SEQ ID NO:22-42, as presented in the Sequence Listing, embrace the equivalent RNA sequences, wherein occurrences of the nitrogenous base thymine are replaced with uracil, and the sugar backbone is composed of ribose instead of deoxyribose" (*see* paragraph [0205] in the published patent application).

Furthermore, the specification teaches the following with regard to complementary sequences: "Sequences complementary to the LIPAM-encoding sequences, or any parts thereof, are used to detect, decrease, or inhibit expression of naturally occurring LIPAM. Although use of oligonucleotides comprising from about 15 to 30 base pairs is described, essentially the same procedure is used with smaller or with larger sequence fragments. Appropriate oligonucleotides are designed using OLIGO 4.06 software (National Biosciences) and the coding sequence of LIPAM. To inhibit transcription, a complementary oligonucleotide is designed from the most unique 5' sequence and used to prevent promoter binding to the coding sequence. To inhibit translation, a complementary oligonucleotide is designed to prevent ribosomal binding to the LIPAM-encoding transcript" (*see* paragraph [0393] in the published patent application).

Accordingly, the specification provides a complete description of the invention as claimed. The rejection is thus moot. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

VII. The Rejection Under 35 U.S.C. § 102

The Office Action, at pages 7-8, rejects claims 98, 101-103, 105-106 and 118 under 35 U.S.C. § 102(b) as allegedly being anticipated by Drayna *et al. Nature 327*: 632-34 (1987)

("Drayna"). According to the Office Action, Drayna discloses an amino acid sequence displaying 97.4% identity to SEQ ID NO:6 and encoded by a DNA sequence displaying 96.8% identity to SEQ ID NO: 27. Applicants respectfully traverse this ground of rejection.

As the pending claims are amended to delete the recitation of biologically active and immunogenic fragments of SEQ ID NO:6, isolated polynucleotides encoding the fragments and isolated polynucleotides displaying 90% identity to SEQ ID NO: 27 or comprising a portion of SEQ ID NO: 27, this rejection is now moot. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

VIII. Allowable Subject Matter

Applicants thank the Examiner for indicating that claim 99 would be allowable if rewritten in independent form.

Claim 99 is now an independent claim and claims 101, 105 and 118 depend from claim 99. Applicants believe that the present application is now in condition for allowance. A notice to this effect is earnestly solicited.

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed or rendered moot. Thus, the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date March 5, 2008 By _____

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